California Department of Health Services
Cancer Research Section
Fiscal Year 1999-2000

REQUEST FOR APPLICATIONS (RFA)

TRANSLATIONAL CANCER RESEARCH AND TECHNOLOGY TRANSFER

Important Dates:

RFA released	August 25, 1999
Application forms available	August 25, 1999
Applications due	October 13, 1999 (5:00 P.M.)
Completion of application review	February 9, 2000
Final selection of awards	March 30, 2000
Final negotiations	April, 2000
Award funds	May 1, 2000

Background and General Priorities

The California Department of Health Services (DHS), Cancer Research Section (CRS) has received a $2.5 million legislative augmentation for cancer research in fiscal year (FY) 1999-2000. CRS will make these funds available to California researchers for translational cancer research and technology transfer.

Given the primary emphasis on basic biomedical cancer research at the federal level, there is an enormous need for translational research to determine how recent laboratory and clinical advances in tertiary medical care can be translated in a compressed time frame to the vast majority of Californians. Specifically, research funding through the National Cancer Institute (NCI) has shifted dramatically to focus on basic genetic and cellular aspects of cancer. The purpose of this RFA is to facilitate the transfer of the resultant technology, including advances in cancer and genetics, into primary care settings.

In addition to the above, since our ethnically and culturally diverse, socio-economically disadvantaged, and medically underserved populations are disproportionately represented in cancer incidence and mortality rates, CRS has a stated and explicit priority directed toward these high-risk populations.

FY 1999-2000 Research Priorities

CRS encourages applicants to submit grant applications that address the general priority area of translational methods research and technology transfer, including behavioral, economics, health policy, managed care, and health care delivery research.

Potential specific areas of investigation include research applications that examine cancer patient decisions to seek testing or types of care. Other areas for which applications are sought include determination of the existence of potential cultural, linguistic, and economic constraints and barriers to optimal health care delivery modes. In addition, applications are solicited that examine the ethical issues associated with genetic testing in cancer care, and the creation of programs or policies designed to improve access of currently underserved and socio-economically disadvantaged populations to cancer information, screening and treatment.

Responsive applications would also include those that seek to systematically assess and report on the current state of the science, state of the art, and state of the practice of cancer control, and to identify and report on promising areas for future research investigations and investment in California. Applications that seek to identify methods that effectively and efficiently communicate current consensus on cancer research and care to the medical community and public at large are also being sought. Applications focusing on cancer prevention policy research at local, institutional, or state levels which may include communications and advocacy, public opinion, and policy maker research are encouraged. Applications are also sought that seek to investigate cancer and cancer care using approaches that encompass outcomes based on research or evidence-based medicine as well as investigating translational research issues related to cancer.

In this funding cycle, CRS would specifically like to fund research emphasizing technology transfer of genetic risk-assessment screening and counseling protocols into primary care settings. Proposals are solicited that seek to identify hereditary cancer resources, to assess epidemiologically-based questionnaires and methods of family history collection, and to collect and evaluate information on referral methods and patterns. In addition, proposals are solicited for the development and evaluation of curricula for hereditary cancer counseling, for the development and evaluation of clinical practice guidelines for hereditary colorectal or other hereditary cancers, and for studying reimbursement and cost-benefit issues in application of hereditary cancer screening.

Subject Areas and Award Mechanisms

For FY 1999-2000, CRS has allocated approximately $800,000 for research proposals focusing on technology transfer relating to cancer and genetics, with the remaining $1.5 million allocated for proposals addressing technology transfer of basic cancer research in general. Awarding the full amount of $800,000 to proposals relating to cancer and genetics is contingent upon CRS receiving a sufficient number of applications ultimately obtaining fundable scores in this area following our peer review process. If a sufficient number of applications which address cancer and genetics and which wind up with fundable scores are not received, the balance of unallocated funds will be added to the pool of funds for the general technology transfer portion of this RFA.

Similarly, if a sufficient number of applications which eventually receive fundable scores are not obtained in response to this overall RFA, the balance of funds may be added to DHS' Cancer Research Program (CRP) extramural or intramural RFA pool for FY 1999-2000. Finally, investigators from the California Cancer Registry are excluded from applying for this RFA.

Approximately $2.5 million is available for this RFA. The amount available is subject to adequate legislative appropriation and expenditure authority.

Specific subject areas:

- Approximately $450,000 per year in total costs is available for up to 3 years for proposals focusing on technology transfer to primary care settings of basic and clinical science research relating to cancer and genetics, as described above.

- Up to $350,000 per year in total costs is available for up to 3 years to establish a Center for Technology Transfer and Translational Research in Cancer and Genetics. The goal of this center should be to bring together basic science and clinical research faculty in multiple fields to enhance the effectiveness of cancer and genetics technology transfer. The Center may focus on, but is not limited to: (a) demonstrations of risks and benefits of population screening; (b) evaluation of specific hereditary cancer units; (c) defining and assessing the effectiveness of interventions for hereditary cancer or cancers with possible genetic associations; and (d) development and evaluation of educational materials in programs for primary care of the general public to translate what is known and useful in cancer and genetics research. Disciplines involved may include: oncology, primary care, genetics, molecular biology, epidemiology, behavioral sciences, preventive medicine, health care delivery, communications, economics, and education. CRS, at its discretion, reserves the right to fund one or no such centers based upon the scientific merit of the applications as determined by the peer review process.

- At least $1.5 million will be available for proposals focusing on technology transfer of any cancer research.

- Furthermore, purchase of capitol equipment above the ordinary will be permitted, provided the application justifies how this equipment will be utilized pursuant the requirements of this RFA.

Award mechanisms: The funding mechanisms for this RFA are described below. All amounts listed below are for direct costs only. Indirect costs may be charged up to 25 percent of the total modified direct costs. Personnel may receive salary support up to a maximum that equals the NCI salary cap ($125,900), prorated according to their percent effort.

- **Investigator-Initiated Award (IIA; $250,000/year maximum; three years maximum duration for initial award; eligible for noncompetitive renewal for an additional two years).**

  This is the award mechanism for investigator initiated projects. Applicants must explain their applications in detail, listing the qualifications of the investigator and describing adequately the general objectives and specific aims of the proposal, the methods of procedure, the significance of the proposed research, the available facilities, and previous related work by other researchers. Applicants must provide a budget estimate with adequate justification of individual items.

- **Pilot and Feasibility Study Award (PFSA; $75,000/year maximum, two years maximum duration).**

  PFSA funding is intended for applications encompassing developmental, exploratory or pilot research. These awards are designed to support research for which limited data are available but where results of the study will have a major impact on the area of study, and that the generation of additional data will permit a more informed assessment of the research's potential validity and importance. Awards will be based on documentation in the grant application that the research approach proposed for funding will have a potentially significant impact on cancer risk factor identification and modification, treatment, psychosocial or economic concerns, as well as either:

  - a very high potential for either direct scientific payoff within the term of the grant; or

  - that the funding provided will permit the generation of sufficient data to permit an application for extramural funding for a full-scale study to be competitive.

- **New Investigator Award (NIA; $75,000/year maximum, three years maximum duration**). **This award mechanism is limited to investigators who have less than five years experience as an independent investigator.**

  NIAs are designed to support newly independent investigators to enable initiation of their own cancer research programs. This mechanism is available only to individuals with M.D., Dr.PH, Ph.D., or equivalent degrees, who have just completed or are in the process of completing postdoctoral fellowships, or individuals who are entering cancer research careers from clinical practice or other related non-research activities. While the application, as with other grants in this Program, will be reviewed and ranked primarily based on the scientific merit of the submitted proposal, additional documentation regarding the applicant's status as a new investigator (including evidence that the institution sponsoring the applicant has provided the applicant with a non-temporary appointment and sufficient resources and support to successfully complete the proposed research), and previous accomplishments, as well as indications of future potential for success as an independent scientist, will be solicited and factored into funding decisions.

- **Community-Initiated Research Collaboration Award (CIRCA).**

  The CRC's goals include the solicitation, funding and performance of research wherein the particular communities directly affected by the questions driving the research should be active participants in the framing of these issues, both in terms of priorities as well as the methodology used. In addition, these groups should not only have a role in the planning of the research but they should have a mechanism to ensure their ongoing participation in the gathering and interpreting of data, and in communicating the findings to their members as well as the broader group of interested parties. Having recognized the importance of these issues, CRP has developed the CIRCA type of award to bring community members and experienced research scientists together to study cancer-related issues. It is the CRC's as well as the CRP's belief that the combination of the knowledge and interest of communities with the expertise and resources of research scientists will stimulate new, innovative and important research that will be rapidly translated into a reduction of the impact of cancer, particularly gender-specific cancers such as prostate and ovarian.

  As involvement of private industry in CRP is a stated intent of the legislation, innovative research linkages between the public and private sectors are encouraged. The primary objective of this mechanism is to bring together various groups interested in cancer control and establish the structure for a collaborative mechanism for research. The collaborative mechanism described should include procedures and protocols to be used to: (a) identify the research questions or issues of interest to the collaborating parties; (b) ensure that the research questions that will be addressed as well the methods to be employed are relevant and appropriate to the community; and (c) ensure that the results of the collaboration will be valid and meaningful to the community. Given the nature of this award (e.g., community and researcher collaboration, processes to be employed identifying appropriate research approaches and targets, etc.), additional supporting information will be required and will subsequently be used to evaluate applications seeking funding via this mechanism

  - **CIRCA-Pilot ($100,000/year maximum, one year planning grant maximum duration).**

    The Pilot CIRCA mechanism is designed to provide the initial funding for the establishment of research collaborations and to develop preliminary research data to allow the collaboration to successfully compete for subsequent funding. This award is to develop the project, solidify the collaborative aspects and collect preliminary data. The specific aims and methods for the Pilot CIRCA will be less well developed and are therefore expected to rely much more heavily on the applications narrative to demonstrate the ability to execute the proposed research.

Proposal Review

Evaluation of complete applications will focus on the quality of the application, particularly the clarity and appropriateness of the material presented in response to the information requested. A primary evaluation criterion is responsiveness to the RFA's research priorities. Responsiveness will be evaluated initially by CRS staff, and applications that appear non-responsive will be forwarded with this notation to the peer review committees for potential disqualification.

As specified above in this RFA, a strong preference will be given to applications that address populations at high risk, e.g., the ethnically and culturally diverse, the medically underserved, the socio-economically disadvantaged, and the designated research priority areas.

The major factor evaluated in every proposal will be its true translational potential, i.e., how can we accelerate the transfer of current technology from the research laboratory and the tertiary care medical centers to the primary care settings where the vast majority of Californians receive their health care.

The primary evaluation criterion, after responsiveness, will be the scientific merit of the proposed research. Study Sections will assess each proposal's merit based upon the following criteria:

Innovation-30%: The proposal will be reviewed and an assessment made as to the extent to which the proposed research's basic concept and hypotheses represent a new and potentially useful way of formulating, investigating, or evaluating the cancer-related problem under consideration.

Approach-15%: The proposal will be reviewed and an assessment made as to the extent to which the proposal delineates mechanisms or approaches that are appropriately matched to the overall goal of the proposal.

Impact-15%: The proposal will be reviewed and an assessment made as to the extent to which the project, if successfully carried out, would make an original and important contribution to the ability to eliminate or mitigate the incidence, morbidity and mortality associated with cancer.

Feasibility-25%: Feasibility will be reviewed and the applications rated as to the likelihood that the proposed work can be accomplished by the investigators, given their expertise, experience, preliminary data (if any are available), and the resources available to the investigators. Included in this criteria will be an assessment of the level of institutional commitment to the proposal and investigator. Institutional commitment should maximize the resources ultimately available to the project

Focus on Medically Underserved and Socio-economically Disadvantaged-15%: The proposal will be reviewed and an assessment made as to the extent to which the proposal addresses cancer prevention, control, and treatment in these high risk populations.

Specific Award Evaluation Criteria

CIRCA Applications

The following collaboration elements will be evaluated as appropriate for the Pilot CIRCA applications:

- the clarity of the definition of the community of interest;
- the relative level of control and participation in all phases of the research by the community members and researchers, including management of grant funds;
- the origination of the research questions;
- the level of support for the research in the community;
- the potential for the research project to facilitate learning and further collaboration;
- the level to which the community partners' knowledge is integrated into planning and conducting the research;
- the extent to which procedures have been established for resolving disagreements among the collaborators;
- the potential benefit to the target community of the expected research outcomes;
- at least one or more co-PI is a research scientist with documented expertise to the proposed research;
- the integration of the community partners' knowledge into and a high degree of shared governance with respect to all phases of the research between the community representatives and researchers particularly with respect to grant funds; and
- the potential exists for an immediate impact on cancer in California.

NIA Applications

Career Development:

- The potential of the research problem and institutional environment to foster an independent research career in cancer for the investigator.

How to Apply

Application forms to be used for this RFA are the same as used for applying to the CRP. Please refer to the CRP Application Packet for specific instructions on how to apply including the development of your research plan.

Application packets along with forms are available from:

1. Your institution's contracts and grants office.

2. On the web in downloadable, executable format at the CRP website, **www.dhs.ca.gov/crp**.

3. By requesting from the CRP office via fax, mail, or e-mail:

Department of Health Services
Cancer Research Program
611 North 7th Street, MS CRP-26
P.O. Box 942732
Sacramento, CA 94234-7320

E-mail: crp@dhs.ca.gov
Fax: (916) 324-9320

Please indicate Request For Application Packet on subject line of all correspondence.

For further information regarding this RFA, please contact CRS at (916) 445-6455 or 445-9302 (voice mail) and/or email at crp@dhs.ca.gov. Grants resulting from this RFA will be directly administered by CRS staff.

Appeals

Only those investigators or organizations that submit an application that is reviewed and not funded may appeal. There is no appeal process for applications that are submitted late or are incomplete. Grounds for appeals shall be limited to assertions that the CRS failed to correctly apply the standards for reviewing and evaluating applications as specified in the RFA. The applicant must file a full and complete written appeal, including the issue(s) in dispute, the legal authority or other basis for the protester's position and the remedy sought. Appeals must be submitted within 45 days of the date of the letter sent to the applicants which contain reviewers' comments. These appeals must be sent to the Chief, Chronic Disease and Injury Control Division (CDIC), c/o the Cancer Research Section, California Department of Health Services. Faxes are not acceptable.

Letters of appeal are to be addressed to:

Donald O. Lyman, M.D., Chief
Chronic Disease and Injury Control Division
c/o Cancer Research Section
California Department of Health Services
611 North 7th Street, MS CRP-26
P.O. Box 942732
Sacramento, CA 94234-7320

At his sole discretion, the Chief of the Division of Chronic Disease and Injury Control (CDIC) may hold hearings with the appellants to discuss the appeals, or make a decision based on the written appeal or both. The decision of the CDIC Chief shall be the final administrative remedy. Within ten (10) working days of receipt of the written appeal, CRS staff will contact the appellant regarding whether or not the appellant desires an in-house hearing or only a written response. Within ten working days of either a hearing or notification by the appellant that a hearing is not desired, the appellant will receive final written decision from the CDIC Chief.